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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,195	05/24/2001	William L. Hunter	110129.420C2	3009

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

13

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application N .

09/865,195

Applicant(s)

HUNTER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 8,13,14 and 78-82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-6,8,9,11-57,66-120,134-182,201-208,220-222,230-232,239-242,247-253,255-258,262-266,271,273-275,278-281,286,288-291,294,298,300-303,309,311-313,321-323,328,330,331,336,338-341,346-348,353,354 and 358-372.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-4,6,10,13,14,16,17,21-56,88,93-112,134-181,202-206,231,232,239-242,247-253,255-258,262-266,271,273-275,278-281,286,288-291,294,298,300-303,309,311-313,321-323,328,330,331,336,338-341,345-348,353 and 367-372.

Continuation of Disposition of Claims: Claims rejected are 1,5,9,11,12,15,18-20,57,66-77,83-87,89-92,113-120,182,201,207,208,220-222,230 and 358-366.

Claim Objections

1. Claims 8, 11, 13 and 14 are objected to because of the following informalities:

The claims refer to cancelled Claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 87 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 87 and 89 recite the limitation "the wire" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 5, 12, 15, 18-20, 57, 66-77, ~~92~~, ~~113~~, 182, 201, 207, 208, 220, 221, 222, 230 and 358-366 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al in view of Brem et al ('986).

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Slater et al disclose radioactive therapeutic seeds and spacers for separating the seeds and further disclose; the radioactive source is selected from I-125, Pd-103, Ir-192, Co-60, Cs-137 and Ru-106; the radioactive source comprises a plurality of seeds; the radioactive source is positioned into a pre-existing or created body cavity adjacent to a site to be treated by radiation; the radiation prevents cellular proliferation; the cellular proliferation is due to cancer; the radioactive source is administered within a body cavity; the radioactive source is administered directly into a body tissue; the disease of the prostate is prostate cancer; the spacer is positioned between adjacent seeds, the spacers holding the adjacent seeds apart and holding the plurality of seeds together as part of a continuous thread; and the seeds and spacers are sized to be received in a catheter for insertion into the tissue. See Column 1, lines 15-22 and 54-58; and Column 7, lines 35-54.

Even though Slater et al disclose a bioabsorbable spacer for use with the radioactive seeds, Slater et al fails to disclose a polymer with a cell-cycle inhibitor; the polymer comprises poly(lactic acid); the cell-cycle inhibitor is an alkylating agent; and the cell-cycle inhibitor comprises paclitaxel.

Brem et al disclose controlled local delivery of chemotherapeutic agents for treating solid tumors and further disclose a polymer with a cell-cycle inhibitor; the polymer comprises poly(lactic acid); the cell-cycle inhibitor is an alkylating agent; and the cell-cycle inhibitor comprises paclitaxel. See Column 5, lines 25-49; and Column 7, lines 32-49.

Since both Slater et al and Brem et al disclose means for treating tumors, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Slater et al to include the use of a biodegradable polymer with a cell-cycle inhibitor, as per the teachings of Brem et al, since it would provide a means of providing localized radiation and chemotherapy at a tumor site.

7. Claims 9, 11, 83-86, 90, 91 and 114-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al and Brem et al ('986) as applied to claims 19 and 92 above, and further in view of Mavity et al ('057).

Slater et al and Brem et al, as discussed above, disclose means for providing localized radiation and chemotherapy to a tumor site, but fail to disclose the use of a cell-cycle inhibitor carried by the outer member on the radioactive seed; the outer member is a coating at least partially covering the outer surface of the seed; the coating is a polymeric material and the cell-cycle inhibitor is within the polymeric material; the cell-cycle inhibitor is absorbed by the polymeric coating; the cell-cycle inhibitor is chemically linked to or coated on the seed; and the carrier material releases the cell-cycle inhibitor when the seeds are in the body cavity.

Mavity et al disclose absorbable brachytherapy and chemotherapeutic delivery devices and methods and further disclose a cell-cycle inhibitor carried by the outer member on the radioactive seed; the outer member is a coating at least partially covering the outer surface of the seed; the coating is a polymeric material and the cell-cycle inhibitor is within the polymeric material; the cell-cycle inhibitor is absorbed by the polymeric coating; the cell-cycle inhibitor is chemically linked to or coated on the seed; and the

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carrier material releases the cell-cycle inhibitor when the seeds are in the body cavity.

See Column 4, lines 57-67; Column 6, lines 13-26; Column 7, lines 6-11; Column 11, lines 38-57; Column 12, lines 31-33.

Since Slater et al, Brem et al and Mavity et al disclose means for delivering localized radiation and chemotherapeutic substances to a tumor site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Slater et al and Brem et al to include the use of a coating on the radioactive seed for delivering the cell-cycle inhibitor, as per the teachings of Mavity et al, since it would provide a means of delivering radiation and a chemotherapeutic agent to the exact same spot rather than have a chemotherapeutic agent adjacent a radioactive seed.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 5, 9, 11, 12, 15, 18-20, 57, 66-77, 83-87, 89-92, 113-120, 182, 201, 207, 208, 220-222, 230 and 358-366 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

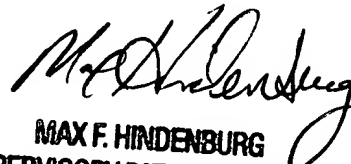
9. Claims 78-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

BS

June 30, 2003


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